

**REMARKS**

Claims 34-43 and 50-68 are pending and are currently under consideration. Applicant adds claim 69. Support for this claim may be found in paragraph [0153].

**Rejections under 35 USC § 112 - I**

Claims 34-43, and 50-68 are rejected under 35 U.S.C. §112 1st paragraph. The Office Action asserts that support for amendments to 34 and 59, which include "first and second surfaces that each engage and conform to respective first and second portions of the target" the first and second surfaces have different porosities, are not found in the application. The Office Action further asserts that "not all of the surfaces necessarily engage the target and nothing of record appears to support that the surfaces of different porosities necessarily engage and conform to the target so one of ordinary skill would not recognize this as the inventive feature.

Applicant disagrees. In addition to the previously cited sections of the subject application, applicant also refers to paragraph 0094, reproduced below:

[0094] Additionally, while ePTFE and porous PET are discussed above as membrane material for use as the encapsulation device, other porous membrane material may be used within the scope of the present invention such as metallic wire mesh or porous Nitinol. More specifically, in one embodiment, the encapsulation device of the present invention may be made from material that is semi-permeable on one side and relatively less permeable or non-permeable on the other side. The more permeable side could be designed to weep some of the more viscous material, such as an adhesive including cyanoacrylate, epoxy, or other bioactive compound, into and/or through the encapsulation device membrane, to preferentially activate or adhere to different areas along the geometry of the encapsulation device. The membrane itself may be dumbbell shaped and have the cavity filled or layered, with channels between the layers filled.

Clearly the specification provides for encapsulation devices with a first side that is semi-permeable and is relatively less permeable second side. In addition, the specification gives clear support for encapsulation devices that are fully expanded within a cavity in tissue. (See e.g, Figs. 36-42 as well as the accompanying text at paragraph 150).

**Rejections under 35 USC § 103 - I**

Claims 34-43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Porter et al. (US 6,547,804) in view of Strother et al (US 4364392). Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness.

The Office Action acknowledges that “Porter et al remains silent as to the first surface has permeability different than a second surface of the porous body so that displacing the first fluid at least the first surface of the porous body is different than the second surface of the porous body.” The Office Action relies on Strother to remedy this deficiency by stating: “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to include a first surface has a permeability different than a second surface of the porous body so that displacing the first fluid at least the first surface of the porous body is different than the second surface of the porous body as taught by Strother et al on the pore balloon of Porter et al in order to release the saline”

Applicant submits that the combination of Porter and Strother is improper. A *prima facie* case of obviousness requires some suggestion or motivation to make the proposed modification. The United States Supreme Court made clear that “[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” KSR, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).”

In the present rejection, the Office Action merely states that the combination is made “in order to release the saline”. However, this falls short of the requirements set forth by the Supreme Court as well as that of the MPEP, in which section §2143 states: “[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.”

In addition to discussing the requirements of the KSR decision, MPEP §2143.01 further states that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.” It is also well established U.S. Patent Law that “[i]f [a] proposed modification would render the prior art

invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (MPEP §2143.01).

Porter, at col. 2, line 43 states that: “[t]he balloon of the invention preferably is both porous and highly distensible. The porous material allows aqueous inflation fluid to pass though the balloon wall at low pressure.” Inflation of the Porter balloon at a low pressure is clearly desirable given the device’s intended purpose to fill aneurysms or other vascular sites. (See Porter Abstract; col. 3, lines 42-66 to col. 5, line 18). Applicant submits that changing a portion of the Porter device to have a varying porosity will also affect the ability of the device to allow fluid to pass through the balloon wall at a low pressure. Clearly, a varying porosity will affect the pressure within the Porter device. For these reasons alone, applicant submits that the modification proposed by the Office Action, would change the explicitly stated principle of the Porter device as well as render it unsuitable for its intended purpose.

In the absence of further rational to support the prima facie case, applicant requests withdrawal of this rejection and believes that the rejection of claims 35-43 should be withdrawn as well.

#### **Rejections under 35 USC § 103 - II**

Claims 52-58 are rejected under 35 U.S.C. §103(a) as being unpatentable over Porter et al. (US 6,547,804) in view of Soltesz (US 6527761).. Applicant disagrees that the Office Action establishes a proper prima face case of obviousness.

Applicant refers to the statement of law on obviousness above. Again, applicant believes the modification of Porter does not provide a valid prima facie case of obviousness. The Office Action concedes that “Porter et al. does not disclose securing a wire reinforcement to an interior surface of the body to assist the body in maintaining the shape.”

The Office Action attempts to remedy this defect using Soltesz with the reasoning that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a wire reinforcement as taught by Soltesz et al in the body of Porter et al in order to assist the body in maintaining the shape.”

Applicant submits that this rational is simply a conclusory statement and provides no articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Furthermore, the addition a wire reinforcement structure to Porter would

appear to defeat the express teachings of Porter, at col. 1, lines 60 to 63: “[t]he balloon wall material is preferably highly distensible so that it can readily conform to the aneurysm at very low pressure inflation and without distention of the aneurysm.” col. 2, line 43, which state that: “[t]he balloon of the invention preferably is both porous and highly distensible.” Applicant submits that any modification affecting the distensible nature of the Porter balloon to maintain a shape appears to contradict the stated purpose of Porter and thus renders the Porter device unsuitable for its intended purpose. Again, applicant refers to the statements of law regarding obviousness above. In the absence of any further reasoning to properly support this combination, applicant believes that this rejection should be withdrawn.

### **Rejections under 35 USC § 103 - III**

Claims 34-51, 59-61 and 63-68 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chobotov (US 6395019) in view of Porter et al and Strother et al.

Again, applicant believes the Office Action fails to establish a proper *prima facie* case of obviousness. The combination of these references appears to be conclusory to simply address the claim requirements rather than provide some rational reason for modification of Chobotov.

The Office Action concedes that Chobotov “does not disclose the body as porous and introducing a second fluid into the porous body to displace the first fluid through the at least the first side of the porous body differently than the second side of the porous body; and allowing the second fluid to cure to secure the porous body to the target.”

The Office Action’s rational for this combination is that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the inflatable porous material of Porter et al for the inflatable portions (55) of the body of Chobotov and utilizing a second curing fluid in order to secure the body to the target (in order not to destroy the Chobotov reference only the inflatable portions, 55 are substituted so that Chobotov would still function as a graft allowing the carrier fluid to release as taught by Strother et al) and as such the second side (inner lumen) of the porous body (fig. 4) would not be permeable.”

The above rational only states that the chambers 58 (of Chobotov) which are actually formed by strips 55 can be porous. Applicant cannot find any articulated reasoning with

some rational underpinning to support the legal conclusion of obviousness as to why one would make this combination. In fact, a review of Chobotov teaches against this modification.

In col. 8, lines 27-44, Chobotov refers to the chambers 58 (that are formed from strips 55) as “fluid tight chambers.” Chobotov even states that “[i]f the material of the strips 55 which have been bonded to the tubular structure 56 are of a permeable character, an additional material may be used to coat the inside of the fluid tight chambers in order to make them impermeable to fluids.” (See Chobotov col. 8, lines 33-37). In lines 37-43), Chobotov further teaches how to make chambers impermeable to fluids.

Again, applicant refers to the above statement of law on obviousness. Clearly, the Office Action is proposing a modification counter to the express teaching of Chobotov without providing any reason as to why one would proceed to ignore the express teachings of Chobotov and modify the device to meet the claims of applicant’s invention. Applicant refers to MPEP §2142 which states “[t]he tendency to resort to ‘hindsight’ based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.”

Here, applicant believes that the failure to provide any rational for modifying Chobotov against its own teachings is based upon the hindsight benefit of applicant’s own disclosure. Accordingly, applicant believes the rejection of claims 34-51, 59-61 and 63-68 should be withdrawn.

## CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. TSNMNE00100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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